IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Application of:	)Performance-Enhancing)Dietary Supplement
Carl W. Hastings et al	)
Serial No. 09/175,748	)Group Art Unit: 1617
Filed 10/20/98	)Examiner: R. Travers

Commissioner of Patents & Trademarks

Washington, D.C. 20231

Sir:

REQUEST FOR INTERFERENCE WITH PATENT
UNDER 37CFR §1.607

Applicants hereby request the declaration of an interference between this application and patent 6,136,339, granted October 24, 2000, to Paul T. Gardiner, for Food Supplements and Methods Comprising Lipoic Acid and Creatine.

Applicants propose the following counts for such interference:

Count 1. A food supplement, comprising lipoic acid or a derivative thereof, and creatine or a derivative thereof.

Count 2. A food supplement according to Count 1, comprising lipoic acid or a salt or ester thereof and creatine or a hydrate, salt or ester thereof.

Count 3. A food supplement according to Count 1, comprising lipoic acid or a derivative thereof and creatine monohydrate.

Count 4. A method for supplementing the diet of an athlete, comprising administering to the diet of the athlete a supplement comprising lipoic acid or a derivative thereof, and creatine or a derivative thereof.

Count 5. A method according to Count 4, wherein the food supplement is mixed with water to provide a liquid drink.

Count 6. A method for enhancing an athlete's muscle size or strength, comprising administering to the diet of the athlete a supplement comprising lipoic acid or a derivative thereof, and creatine or a derivative thereof.

Count 7. A food supplement according to Count 1, further comprising glutamine.

These proposed counts correspond exactly to Claims 1, 2, 3, 14, 24, 25 and 36 of patent 6,136,339 except that the term "count" has been substituted for "claim" in the dependent claims.

In a Preliminary Amendment filed herewith, applicants submit a new set of claims to be substituted for the original claims. Of that set, new Claims 11-14 and 25-27 correspond directly to proposed Counts 1-7, except that the term "claim" rather than "count" appears in the dependent claims.

All of the claims set forth in the preliminary amendment, as well as all of the claims originally presented in this application, call for a food supplement that includes both lipoic acid, specifically alpha lipoic acid, and creatine monohydrate. As an essential ingredient, alpha lipoic acid is indicated as being a potent free radical scavenger and chelator of toxic metals (specification, page 4). It is a coenzyme that participates in converting blood sugar into energy and, in addition, is identified as an antioxidant nutrient that networks with other antioxidants in quenching free radicals (page 11). It is understood that the other antioxidant nutrients function more effectively when there is more of the lipoic acid available than what is tied up in use by

the body as a coenzyme. As stated on page 11, lipoic acid is easily absorbed and is readily bioavailable.

As an essential ingredient in applicants' supplement, creatine is described as helping to reduce muscle fatigue and rebuild lean muscle mass (pages 3,4). On pages 8 and 9, it is explained that enery consumed by muscles is largely in the form of adenosine triphosphate (ATP) and that during short-term, high-intensity exercise the demand by working muscles for ATP increases to several hundred times the requirement of muscles at rest. Since ATP can be stored only to a limited extent in muscle cells, maintaining peak performance requires constant replenishment of ATP levels. The primary resupplier of ATP levels for short-duration, high-intensity exercise is the amino acid creatine, about 60% of which is stored in skeletal muscle tissue in the form of creatine phosphate. During muscle contraction, creatine phosphate converts to adenosine triphosphate (ADP) to ATP, thereby replacing the ATP consumed during exercise.

As stated on page 9, neither creatine phosphate nor ATP can be directly supplemented in the diet; however, higher levels of creatine may be derived from creatine monohydrate, a form of creatine which has been shown to raise total plasma levels of creatine. Creatine monohydrate in applicants' dietary supplement shortens the time necessary for the body to generate replacement creatine phosphate and thus significantly reduce muscle recovery time between short-duration, high-intensity activities.

Applicants' Claim 14 also calls for the presence of glutamine. As brought out on page 6, glutamine is known to

promote anabolic conditions in muscle cells and to increate the rate of protein synthesis. It indirectly promotes growth by increasing the hydration state of muscle cells. When cells are swollen with water, the breakdown of protein, glycogen and glucose is inhibited. Glutamine stimulates protein and glycogen synthesis. Conversely, if a cell becomes dehydrated, it shrinks and immediately goes into a catabolic state that breaks down the muscle's vital proteins.

Other composition claims presented in the Preliminary Amendment sets forth other ingredients believed to be critical in applicants' dietary supplement.

New method Claims 25, 26 and 27 find support throughout applicants' disclosure, since that disclosure is concerned in its entirety with a dietary supplement to be orally ingested for enhancing physical performance of human subjects. Essential ingredients in such a dietary supplement are lipoic acid, particularly alpha lipoic acid, and creatine, particularly creatine monohydrate. As stated on page 14, the dietary supplement takes the form of a fine powder that is to be consumed as a beverage, with one to three scoops of the powder (26g to 78g) being mixed with water, juice, milk or any other suitable beverage.

It is to be noted that the effective filing date of applicants' application (October 20, 1998) is less than three months after the filing date of patent 6,136,339 (August 21, 1998). It is therefore submitted that applicants have made a prima facie showing under 37 CFR 1.608(a).

Pursuant to 37 CFR 1.608(a), applicants, by their attorney, state that there is a basis upon which applicants are entitled to a judgment relative to the patentee. Accordingly, it is respectfully requested that an interference be declared between this application and patent 6,136,339.

Respectfully submitted

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